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NOTICE OF ALLOWANCE AND FEE(S) DUE

36577 7590 04/06/2009

MEDIMMUNE, LLC
Jonathan Klein-Evans
ONE MEDIMMUNE WAY
GAITHERSBURG, MD 20878

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/06/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,508

03/26/2004

Xing Cheng

NS220US

8613

TITLE OF INVENTION: NUCLEIC ACIDS ENCODING RESPIRATORY SYNCYTIAL VIRUS SUBGROUP B STRAIN 9320

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	07/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

36577 7590 04/06/2009

MEDIMMUNE, LLC
Jonathan Klein-Evans
ONE MEDIMMUNE WAY
GAITHERSBURG, MD 20878

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,508	03/26/2004	Xing Cheng	NS220US	8613

TITLE OF INVENTION: NUCLEIC ACIDS ENCODING RESPIRATORY SYNCYTIAL VIRUS SUBGROUP B STRAIN 9320

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	07/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHEN, STACY BROWN	1648	536-023720

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/06/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/811,508	CHENG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/29/08.
2. ☒ The allowed claim(s) is/are 1,2,4,10-12,14-16,19,20,67,70,72,75,76 and 78.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>pages 2-3 only of IDS 12/14/04</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
|--|---|

Art Unit: 1648

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

IN THE SPECIFICATION:

The existing title has been replaced with the following:

--Nucleic Acids Encoding Respiratory Syncytial Virus Subgroup B strain 9320--

Authorization for the following examiner's amendment was given in a telephone interview with Robin Quartin on November 20, 2008.

The application has been amended as follows:

IN THE CLAIMS:

Claims 1 and 20 have been amended; see attached claim listing.

Claims 71, 73 and 77 have been cancelled.

Examiner's Comment and Reasons for Allowance

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 29, 2008 has been entered.

Art Unit: 1648

Applicant's amendments and arguments have overcome the rejection of the claims under 35 U.S.C. 112, second paragraph.

The title has been amended to reflect the claimed subject matter. Claims 71, 73 and 77 were cancelled, being drawn to non-elected subject matter not eligible for rejoinder. Claims 1 and 20 were amended to cancel non-elected subject matter not eligible for rejoinder.

Conclusion

3. Claims 1, 2, 4, 10-12, 14-16, 19, 20, 67, 70, 72, 75, 76 and 78 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Complete Claim Listing for 10/811,508 with Examiner's Amendment:

Claim 1 (currently amended). An isolated or recombinant nucleic acid comprising at least one artificially mutated nucleotide relative to SEQ ID NO: 1 or the complementary polynucleotide sequence thereof, wherein the mutated nucleotide comprises one ~~[[of]]~~ or more of: a deleted nucleotide, an inserted nucleotide, or a substituted nucleotide, and wherein the nucleic acid comprises:

(a) a polynucleotide sequence that is greater than 97.8% identical to SEQ ID NO: 1 or the complementary polynucleotide sequence thereof, as determined by Nucleotide-Nucleotide Basic Local Alignment Search Tool (BLASTN) using default parameters, wherein the polynucleotide sequence encodes an infectious, replicating respiratory syncytial virus (RSV); or

(b) a polynucleotide sequence encoding an amino acid sequence or unique subsequence selected from the group consisting of ~~(i) an amino acid sequence that is greater than 99.3% identical to SEQ ID NO:2, (ii) an amino acid sequence that is greater than 98.4% identical to SEQ ID NO:3, (iii) an amino acid sequence that is greater than 99.7% identical to SEQ ID NO:4, (iv) an amino acid sequence that is greater than 98.3% identical to SEQ ID NO:5, (v) an amino acid sequence that is greater than 99.6% identical to SEQ ID NO:6, (vi) an amino acid sequence that is greater than 97.0% identical to SEQ ID NO:7, (vii) an amino acid sequence that is greater than 99.3% identical to SEQ ID NO:8, (viii) (i) an amino acid sequence that is greater than 99.5% identical to SEQ ID NO: 9, and (ix) (ii) an amino acid sequence that is greater than 96.4% identical to SEQ ID NO: 10, and (x) an amino acid sequence that is greater than 99.2% identical to SEQ ID NO:11,~~ as determined by BLASTP using default parameters, wherein an RSV that comprises the amino acid sequence is infectious and replicating.

Claim 2 (previously presented). The nucleic acid of claim 1, wherein the nucleic acid is selected from the group consisting of a DNA, a cDNA, an RNA, and an artificial nucleic acid.

Claim 3 (canceled)

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Claim 4 (previously presented). The nucleic acid of claim 1, wherein the polynucleotide sequence of (a) is at least 98.5% identical to SEQ ID NO: 1 or the complementary polynucleotide sequence thereof, as determined by BLASTN using default parameters.

Claims 5–9 (canceled)

Claim 10 (previously presented). The nucleic acid of claim 1, wherein at least one polypeptide encoded by the nucleic acid comprises at least one deleted, inserted, or substituted amino acid residue.

Claim 11 (previously presented). The nucleic acid of claim 10, wherein the polypeptide comprises at least one substituted amino acid residue wherein the substitution is a substitution of a first amino acid with a second amino acid wherein the first amino acid and the second amino acid are both within the same one of the following groups of amino acids: (i) Alanine, Serine, and Threonine; (ii) Aspartic acid and Glutamic acid; (iii) Asparagine and Glutamine; (iv) Arginine and Lysine; (v) Isoleucine, Leucine, Methionine, and Valine; or (vi) Phenylalanine, Tyrosine, and Tryptophan.

Claim 12 (previously presented). The nucleic acid of claim 1, wherein the at least one artificially mutated nucleotide is located in the open reading frame encoding the polypeptide of SEQ ID NO: 12.

Claim 13 (canceled)

Claim 14 (previously presented). The nucleic acid of claim 1, wherein the open reading frame encoding the polypeptide of SEQ ID NO: 12 is deleted, or wherein the open reading frame encoding the polypeptide of SEQ ID NO:10 is deleted.

Art Unit: 1648

Claim 15 (previously presented). The nucleic acid of claim 12, wherein the at least one artificially mutated nucleotide comprises a deletion, and wherein the nucleotides encoding amino acid residues 164 – 197 of SEQ ID NO: 12 are deleted.

Claim 16 (previously presented). The nucleic acid of claim 1, wherein the at least one artificially mutated nucleotide is located in the open reading frame encoding the polypeptide of SEQ ID NO: 10.

Claims 17-18 (canceled)

Claim 19 (original). The nucleic acid of claim 16, wherein at least one of the nucleotides encoding amino acid residue 1, amino acid residue 4, amino acid residue 10, or a combination thereof, of SEQ ID NO: 10 is mutated.

Claim 20 (currently amended) The nucleic acid of claim 1, wherein the unique polynucleotide subsequence of (b) comprises at least one complete open reading frame which encodes a polypeptide selected from the group consisting of SEQ ID NOs: 2-12 9 and 10; or comprising a plurality of complete open reading frames.

Claims 21-66 (canceled)

Claim 67 (previously presented). An isolated or recombinant nucleic acid comprising at least one artificially mutated nucleotide relative to SEQ ID NO: 1, wherein the mutated nucleotide comprises one or more of: a deleted nucleotide, an inserted nucleotide, or a substituted nucleotide, and wherein the nucleic acid comprises at least one unique polynucleotide subsequence comprising at least 500 contiguous nucleotides of SEQ ID NO: 1 or the complementary polynucleotide sequence thereof.

Claims 68-69 (canceled)

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Claim 70 (previously presented). The nucleic acid of claim 67 wherein the nucleic acid comprises at least one unique polynucleotide subsequence comprising at least 1000 contiguous nucleotides of SEQ ID NO: 1.

Claim 71 (canceled)

Claim 72 (previously presented). The nucleic acid of claim 67, wherein the nucleic acid further comprises at least one polynucleotide subsequence from a different strain of virus, at least one polynucleotide subsequence from a different strain of human RSV, or at least one polynucleotide subsequence from a different species of virus.

Claim 73-74 (canceled)

Claim 75 (previously presented). The isolated or recombinant nucleic acid of claim 1, wherein the isolated or recombinant nucleic acid comprises a polynucleotide sequence encoding an amino acid sequence that is greater than 99.5% identical to SEQ ID NO: 9.

Claim 76 (previously presented). The isolated or recombinant nucleic acid of claim 75, wherein the amino acid sequence is the amino acid sequence of SEQ ID NO: 9.

Claim 77 (canceled)

Claim 78 (previously presented). The nucleic acid of claim 67 wherein the unique polynucleotide subsequence encodes at least 50 contiguous amino acid residues of SEQ ID NO: 10.

/Stacy B Chen/
Primary Examiner, Art Unit 1648